(3)

No. 98-1768

Supreme Court, U.S.
FILED
JUN 1 1999
CLERK

In the Supreme Court of the United States

OCTOBER TERM, 1998

THE BUCKMAN COMPANY,

Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,

Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Third Circuit

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

JOHN J. CUMMINGS, III
Cummings Cummings & Dudenhefer
416 Gravier Street
New Orleans, LA 70130
(504) 586-0000

ARNOLD LEVIN
MICHAEL D. FISHBEIN*
* *Counsel of Record*
SANDRA L. DUGGAN
MICHAEL S. TARRINGER
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, PA 19106
(215) 592-1500

Counsel for Respondent

36pp

RULE 29.6 STATEMENT

Pursuant to Supreme Court Rule 29.6, Respondent states that it has no parent companies or non-wholly owned subsidiaries.

TABLE OF CONTENTS

Page

RULE 29.6 STATEMENT i

TABLE OF AUTHORITIES iii

INTRODUCTION 1

THE FACTS 2

A. The Regulatory Background 2

B. Buckman's Fraud 6

C. The Proceedings Below 10

REASONS TO DENY THE WRIT 12

A. The Question Presented by Petitioner is Not an Issue in this Case 12

B. The Court of Appeals Decision Represents a Straightforward Application of a Recent, Unanimous Ruling by this Court 13

C. There is No Substantial Appellate Conflict Concerning Whether "Fraud-on-the-FDA" Claims are Preempted 21

D. This Case Does Not Present an Appropriate Vehicle to Resolve Any Conflict Regarding the Issue of Whether an FDA Marketing Approval Can Preempt State Laws of General Applicability 24

CONCLUSION 26

TABLE OF AUTHORITIES

Federal Cases **Page(s)**

Chambers v. Osteonics Corp., 109 F.3d 1243 (7th Cir. 1997) . . . 21

Church of Scientology of California v. Richardson, 437 F.2d 214 (9th Cir. 1971) 3

Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992) 20

Committee of Dental Amalgam Manufacturers and Distributors v. Stratton, 92 F.3d 807 (9th Cir. 1996), *cert. denied*, 519 U.S. 1084 (1997) 21

Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324 (4th Cir. 1996) 21, 25

English v. Mentor Corp., 67 F.3d 477 (3d Cir. 1995), *vacated*, 518 U.S. 1030 (1996) 14, 15

Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132 (1963) 19, 20

Freightliner Corp. v. Myrick, 514 U.S. 280 (1995) 19, 20

Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994) 14, 15

Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999) . . . 21

Hall v. Beals, 396 U.S. 45 (1969) 13, 25

Hawkins v. Upjohn Co., 890 F. Supp. 609 (E.D. Tex. 1994) . . . 10

Federal Cases (Cont.) **Page(s)**

Hines v. Davidowitz, 312 U.S. 52 (1941) 19, 20

Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs, Dept. of Labor, 519 U.S. 248 (1997) 13

King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993) 14, 15

Kuiper v. American Cyanamid Co., 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1839 (1998) 22

Lake v. U.S. Food & Drug Administration, 1989 WL 71554 (E.D. Pa. June 27, 1989) 3

Learjet Corp. v. Spenlinhauer, 901 F.2d 198 (1st Cir. 1990) . . . 10

Lewis v. Brunswick Corp., 107 F.3d 1494 (11th Cir. 1997), *cert. dism'd*, 118 S. Ct. 1793 (1998) 22

Liles v. Oregon, 425 U.S. 963 (1976) 1

Lohr v. Medtronic, Inc., 56 F.3d 1335 (11th Cir. 1995), *aff'd in part, rev'd in part*, 518 U.S. 470 (1996) 14, 15

Martin v. American Medical Systems, Inc., 116 F.3d 102 (4th Cir. 1997) 21

Martin v. Telectronics Pacing Systems, Inc., 105 F.3d 1090 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998) 25

Federal Cases (Cont.) **Page(s)**

McDermott v. State of Wisconsin, 228 U.S. 115 (1913) 19

Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) . . . . . passim

Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995), *rejected by Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *overruled by, In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3rd Cir. 1998) . . 14, 15, 23

Mitchell v. Collagen Corp., 67 F.3d 1268 (7th Cir. 1995), *vacated*, 518 U.S. 1030 (1996) 14, 15

Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) 1, 22, 23

Moore v. Kimberly-Clark Corp., 867 F.2d 243 (5th Cir. 1989) . . 19

National Bank of Commerce of El Dorado v. Kimberly-Clark Corp., 38 F.3d 988 (8th Cir. 1994) 15

Oja v. Howmedica, Inc., 111 F.3d 782 (10th Cir. 1997) . . . 21, 24

In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817 (3d Cir. 1998) 22

Papike v. Tambrands Inc., 107 F.3d 737 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997) 24

Princeton University v. Schmid, 455 U.S. 100 (1982) 13, 25

Federal Cases (Cont.) **Page(s)**

Reeves v. AcroMed Corp., 44 F.3d 300 (5th Cir.), *cert. denied*, 515 U.S. 1104 (1995) 14, 15

Reeves v. AcroMed Corp., 103 F.3d 442 (5th Cir. 1997) 21

Rivers v. Roadway Express, Inc., 511 U.S. 298 (1994) 13

Seminole Tribe of Florida v. Florida, 517 U.S. 44 (1996) 13

Stanton by Brooks v. Astra Pharmaceutical Products, Inc., 718 F.2d 553 (3d Cir. 1983) 10

Symens v. SmithKline Beecham Corp., 152 F.3d 1050 (8th Cir. 1998) 21

Talbott v. C.R. Bard, Inc., 63 F.3d 25 (1st Cir. 1995), *cert. dism'd*, 517 U.S. 1230 (1996) 15

United States v. 250 Jars, etc., 344 F.2d 288 (6th Cir. 1965) 3

United States v. An Article ... Consisting of 216 Cartoned Bottles More or Less, 409 F.2d 734 (2d Cir. 1969) 3

United States v. An Article of Device...Diapulse, 768 F.2d 826 (7th Cir. 1985) 2

United States v. Rutherford, 442 U.S. 544 (1979) 4

Washington Legal Foundation v. Friedman, 13 F. Supp.2d 51, 56 (D.D.C. 1998), *order amended by* 36 F. Supp.2d 16 (D.D.C.), *amended by* 36 F. Supp.2d 418 (D.D.C. 1999) 4

Federal Cases (Cont.) **Page(s)**

Weinberger v. Hynson Westcott & Dunning, Inc., 412 U.S. 609 (1973) 4

State Cases

Armstrong v. Optical Radiation Corp., 57 Cal.Rptr.2d 763 (Cal. App. 1996) 21

Baird v. American Medical Optics, 713 A.2d 1019 (N.J. 1998) . 22

Connely v. Iolab Corp., 927 S.W.2d 848 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997) 19,21,22

Dutton v. AcroMed Corp., 691 N.E.2d 738 (Ohio App. 1997) .. 22

Green v. Dolsky, 546 Pa. 400, 685 A.2d 110 (1996), *cert. denied*, 520 U.S. 1168, 1212 (1997) 16,19,21,22

Niehoff v. Surgidev Corp., 950 S.W.2d 816 (Ky. 1997), *cert. denied*, 118 S. Ct. 1187 (1998) 21

Steele v. Collagen Corp., 63 Cal. Rptr. 2d 879 (Cal. App. 1997) . 21

Walker v. Johnson & Johnson Vision Products Inc., 217 Mich. App. 705, 552 N.W.2d 679 (Mich. App. 1996) .. 21

Federal Statutes, Regulations, Rules and Legislative Materials

18 U.S.C. § 1001 ..... 6, 18

21 U.S.C. § 301 ..... passim

Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 U.S.C. § 321(h) 3

21 U.S.C. § 351(f) 2

21 U.S.C. § 352(o) 2

21 U.S.C. § 360 . . . . . 2, 6

21 U.S.C. § 360c(a)(1)(C) 5, 6

21 U.S.C. § 360c(f) 5

21 U.S.C. § 360c(f)(1) 6, 16

21 U.S.C. § 360c(i) 5

21 U.S.C. § 360c(i)(1)(A) 5, 16

21 U.S.C. § 360e 5

21 U.S.C. § 360e(a) 5

21 U.S.C. § 360e(c) 2

21 U.S.C. § 360e(d)(2) 24

21 U.S.C. § 360j(g) 5, 24

21 U.S.C. § 360k . . . . . passim

21 U.S.C. § 360(k) 5

Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 U.S.C. § 365(d) 2

21 C.F.R. § 130.12 2

21 C.F.R. § 801.4 3

21 C.F.R. § 801.5 3

21 C.F.R. § 807.87(e) 3

21 C.F.R. § 807.87(f) 4

21 C.F.R. § 807.87(j) 6, 18

21 C.F.R. § 807.100 . . . . . 5, 6, 16

21 C.F.R. § 807.100(a)(2) 5

21 C.F.R. § 807.100(b)(1) 3

21 C.F.R. § 812.7(a) 5

21 C.F.R. § 813 . . . . . 5, 24

21 C.F.R. § 814.20 2

21 C.F.R. § 814.20(b)(3)(ii) 3

21 C.F.R. § 888.3070 4

Federal Statutes, Regulations, Rules and Legislative Materials (Cont.) **Page(s)**

21 C.F.R. § 890.3150 3

59 Fed. Reg. 59820 (Nov. 18, 1994) 3

63 Fed. Reg. 40025 (1998) 9

Sup. Ct. R. 10 1

Fed. R. Civ. P. 12(b)(6) 10

1976 U.S. Code Cong. & Admin. News, 1070, 1075 2

S. Rep. No. 33, 94th Cong., 2d Sess. 2

H.R. Rep. No. 853, 94th Cong., 2d Sess. 3

BRIEF IN OPPOSITION TO PETITION FOR A WRIT OF CERTIORARI

INTRODUCTION

This Court repeatedly has articulated a policy of substantial restraint in the exercise of its review powers. *See Supreme Court Rule* 10. Plainly, this policy is not served by granting a writ of certiorari to review an appellate decision which involves the straightforward application of legal principles recently and unanimously announced by this Court. *Liles v. Oregon*, 425 U.S. 963, 964 (1976) (Stevens, J., concurring in the denial of certiorari). However, that is precisely what the instant Petition asks this Court to do.

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), this Court unanimously ruled that there is no preemption of state-law tort claims which are based on conduct that violates the requirements of federal medical device law. *Lohr*, 518 U.S. at 495-97 (majority opinion) & 518 U.S. at 513 (O'Connor, J., concurring in part). Applying that principle in the instant matter, the United States Court of Appeals for the Third Circuit ruled that federal law does not preempt plaintiffs' claims to recover damages under state law for the injuries which they suffered as a result of defendants' misrepresentations to the FDA. *See* Appendix of Petitioner Buckman Company to Petition for a Writ of Certiorari ("App."), 1a-25a. Since that decision represents a direct application of the principle recently and unanimously announced by this Court in *Lohr*, it should not reasonably be subject to question, let alone certiorari review. While it is true that in a prior decision the United States Court of Appeals for the Seventh Circuit held otherwise, it did so only in passing, in reliance on a pre-*Lohr* Third Circuit opinion which was overruled here, and without articulating any reasons for its holding. *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998) ("*Mitchell II*"). All of the other appellate courts that have

considered the issue have ruled, consistent with the decision of the Third Circuit here, that state-law claims predicated upon fraud on the FDA are not preempted. Therefore, any technical division of appellate authority on this issue is not sufficiently substantial or mature to warrant intervention by the Court at this time.

THE FACTS

A. The Regulatory Background

At issue in this multidistrict litigation are medical devices which are subject to regulation by the United States Food and Drug Administration ("FDA") pursuant to the Food, Drug and Cosmetic Act ("FDCA"), 21 *U.S.C.* § 301, *et. seq.*, and the Medical Device Amendments to that Act ("MDAs"), 21 *U.S.C.* § 360, *et seq.* The purpose of the FDCA and the MDAs is to protect members of the unsuspecting public from drugs and devices "which pose serious risk if inadequately tested or improperly designed or used."[1]

One of the central tenets of the legislation is that the existence and character of a drug or device is ultimately determined by the "intended use" of the article, not by its physical characteristics or

---

[1] S. Rep. No. 33, 94th Cong., 2d Sess. 5, reprinted in 1976 *U.S. Code Cong. & Admin. News*, 1070, 1075. *See also, e.g.*, 21 *U.S.C.* §§ 360e(c) & 365(d); 21 *C.F.R.* §§ 814.20 & 130.12; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 475-78 (1996); *Weinberger v. Hynson Westcott & Dunning, Inc.*, 412 U.S. 609, 617-20 (1973); *United States v. An Article of Device...Diapulse*, 768 F.2d 826, 832 (7th Cir. 1985).

physiological effects.[2] Thus, for example, a screw which is intended for use in constructing a car is obviously not a medical "device" subject to any regulation by the FDA. The same screw, if intended for use in constructing crutches, would be a "Class I" medical device subject to minimal regulation. *See* 21 *C.F.R.* § 890.3150. If the same screw was intended for use in the spine, it

---

[2] *See, e.g.*, 21 *U.S.C.* § 321(h) (device defined as any article "which is -- ...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation or prevention of disease, in man or other animals...."); 21 *U.S.C.* § 321(h) ("drug" similarly defined); *Church of Scientology of California v. Richardson*, 437 F.2d 214, 216 (9th Cir. 1971); *United States v. An Article ... Consisting of 216 Cartoned Bottles More or Less*, 409 F.2d 734, 739 (2d Cir. 1969) (a cosmetic, such as shampoo, can be a drug, regardless of its actual physical effects, depending on its intended use); *United States v. 250 Jars, etc.*, 344 F.2d 288, 289 (6th Cir. 1965) (honey classified as a drug when it is sold for therapeutic purposes); H.R.Rep. No. 853, 94th Cong., 2d Sess. at 14-15 ("It is the Committees' intention that each use...be treated as constituting a different device for purposes of classification and regulation"); *Lake v. U.S. Food & Drug Administration*, 1989 WL 71554 at *5 (E.D. Pa. June 27, 1989) ("different uses pose different risks and require new proof of safety and effectiveness"); *Requests for Comments in Regard to Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices*, 59 *Fed.Reg.* 59820 (Nov. 18, 1994).

Accordingly, the intended use of a device specified by the person submitting a request to the FDA for marketing clearance delineates the scope of the FDA's review. *See* 21 *C.F.R.* §§ 801.4, 801.5, 807.87(e), 807.100(b)(1) & 814.20(b)(3)(ii).

would be a "Class III" medical device subject to extensive FDA regulation. *See* 21 *C.F.R.* § 888.3070.

Another key concept at the heart of the federal regulatory scheme arises from the legislative conviction that the safety and efficacy of drugs and devices must be demonstrated in well-controlled clinical trials and cannot be determined based on the anecdotal experience of physicians. *E.g.*, *Weinberger v. Hynson Westcott & Dunning, Inc.*, 412 U.S. 609, 619 (1973) (the "strict and demanding standards [of the FDCA], barring anecdotal evidence indicating that doctors 'believe' in the efficacy of a drug are amply justified by the legislative history [which shows] a marked concern that impressions or beliefs of physicians, no matter how fervently held, are treacherous"); *see also United States v. Rutherford*, 442 U.S. 544, 557-58 (1979) (rejecting arguments that FDA approval requirements for new intended uses could be overcome, even when terminally ill patients were to receive the treatments).[3] Accordingly, the MDAs generally provide that a medical device may not be introduced into commerce unless it

---

[3] The danger of using drugs or devices based on the clinical theories or anecdotal experience of physicians rather than results of well-conducted clinical trials was vividly illustrated in the 1980's when physicians began to prescribe the drug Flecainide, off label, to treat arrhythmias in patients who recently had heart attacks. The drugs were very effective in controlling arrhythmias. However, when well-controlled trials were finally conducted with respect to this "off-label treatment," it appeared that those who took the drug had a two and one-half fold increase in mortality and that 3,000 to 10,000 patients per year had died as a consequence of this "treatment." *See Washington Legal Foundation v. Friedman*, 13 F. Supp.2d 51, 56 (D.D.C. 1998), *order amended by* 36 F. Supp.2d 16 (D.D.C.), *amended by* 36 F. Supp.2d 418 (D.D.C. 1999).

receives "premarket approval" from the FDA based on the outcome of well-controlled clinical trials and extensive FDA review.[4] *See* 21 *U.S.C.* §§ 360c(a)(1)(C) & 360e; *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996).

The principal exception to the premarket approval requirement derives from a congressional concern that manufacturers of devices which were in commerce prior to enactment of the MDAs should not receive a competitive advantage. *Lohr*, 518 U.S. at 477-79 & 493-94. This exception permits the marketing of a Class III device without premarket approval if the FDA determines that the device is "substantially equivalent" to a "predicate device." *See* 21 *U.S.C.* §§ 360(k), 360c(f) & (i); 21 *C.F.R.* § 807.100. A predicate device is one which was commercially distributed prior to May 28, 1976 or which was introduced thereafter and which was reclassified into regulatory Class I or II. *Id.* A device is "substantially equivalent" to a predicate device only if "the device has the same intended use as a predicate device." 21 *U.S.C.* § 360c(i)(1)(A); 21 *C.F.R.* § 807.100(b)(1).

Substantial equivalence, as defined by the statute, is claimed and either accepted or rejected through a premarket notification

---

[4] If a manufacturer wishes to generate the scientific data necessary to obtain premarket approval, it may do so under the investigational device exemption provisions of the FDCA. 21 *U.S.C.* § 360j(g); 21 *C.F.R.* § 813, *et seq.* These provisions authorize the FDA to grant an exemption permitting experimental devices to be used without premarket approval under stringent conditions established and actively supervised by the agency. *Id.* Under FDA regulations, an investigational device may not be promoted for commercial distribution or test marketed outside of the approved IDE. *See* 21 *C.F.R.* § 812.7(a).

submitted under Section 510(k) of the Act, 21 *U.S.C.* § 360(k). By virtue of both federal statutes and FDA regulations, all statements made in connection with a premarket notification must be truthful. *See* 18 *U.S.C.* § 1001; 21 *C.F.R.* § 807.87(j). In addition, a premarket notification must include "proposed labels, labeling and advertisements sufficient to describe the device, its intended use, and the directions for its use" and "a statement indicating that the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement." *See* 21 *C.F.R.* § 807.87(e) & (f). If the FDA determines in response to a 510(k) notification that the device is not substantially equivalent to a lawfully-marketed predicate device, the device may not be marketed unless it receives premarket approval. Marketing of the device without premarket approval would constitute adulteration in violation of the statute. *See* 21 *U.S.C.* §§ 351(f), 352(o), 360c(a)(1)(C), 360c(f)(1) & 360e(a); 21 *C.F.R.* § 807.100(a)(2).

B. Buckman's Fraud

Petitioner, Buckman Company, is a regulatory consultant who was retained by AcroMed Corporation to assist it in obtaining marketing clearance for the Variable Screw Placement ("VSP") Spinal Plate Fixation System. App., 4a. The system was designed as an adjunct to spinal fusion surgery and consisted of plates which were to be attached to the posterior portion of the lumbar spine with screws inserted into the spinal pedicles, the bony archways which flank the spinal cord. *See* Appendix to Plaintiffs' Brief in the District Court, MDL 1014, Docket Item No. 858 (hereinafter "D.Ct.App."), Ex. # 1 at 312-14.

On September 4, 1984 and again on September 20, 1985, Buckman filed premarket notifications for the VSP device, truthfully representing that it was intended for use as a pedicle

screw fixation construct in spinal fusion surgery. App., 4a-5a. In response to each notification, the FDA expressly determined that the VSP Spinal Plate Fixation System was not substantially equivalent to any device marketed in commerce prior to May 28, 1976, and that it posed potential risks not exhibited by other spinal fixation systems including "greater chance of neurological deficit." *Id.* Therefore, the agency advised AcroMed and Buckman that the VSP system could not be commercially distributed without premarket approval. *Id.*

Determined to sell the VSP system as a pedicle screw fixation device, AcroMed and Buckman concocted an unlawful scheme to bring the VSP device components to market without premarket approval. App., 5a. Pursuant to this plan, AcroMed changed the name of the VSP device from a "spinal plate fixation system" to "nested bone plates" and "cancellous bone screws." *Id.* Then, in late December, 1985, Buckman submitted separate premarket notifications for the plates and screws in which Buckman fraudulently omitted all reference to the use of the device in the spine. App., 6a. Instead, these 510(k) notifications falsely represented to the FDA that the device components were substantially equivalent to preamendment Class II devices used to repair fractures of the arms and legs. *Id.* Consistent with this, each 510(k) notification expressly represented to the agency that there was "no new application, indication, material, device configuration or specification presented by" the device components, even though Buckman was aware that AcroMed's intention was to market the device components solely as a spinal fixation construct which the FDA had already decided was a "new application, indication and device configuration" for which 510(k) marketing clearance was not appropriate. D.Ct.App., Ex. #s 7 & 8.

Noting that the nested bone plates and cancellous bone screws were identical to the components of the VSP Spinal Plate Fixation

System which the FDA had previously refused to clear, the FDA sought clarification concerning the intended use of the plates and screws. D.Ct.App., Ex. # 1 at 92-93 & 127; Ex. # 9. On January 10, 1986, Buckman responded to this request, affirmatively representing to the FDA that: "The AcroMed plates are intended for use in appropriate fractures of long bones of both the upper and lower extremity...." App., 5a-6a (*citing* Third Circuit Appendix at A-58); D.Ct.App., Ex. # 9.

There is no question that the representations made by Buckman to the FDA concerning the intended use of AcroMed's plates and screws were fraudulent. Indeed, contemporaneous with the Buckman-AcroMed 510(k) submission to the FDA, AcroMed's President wrote a letter in which he admitted that the submission was "a labeling slight-of-hand that satisfies the agency's regulations but in no way changes the intended use of the plates and screws." D.Ct.App., Ex. # 12; Third Circuit Appendix, No. 97-1783 at A-58. In addition, in an interview with FDA enforcement officials, AcroMed's former Vice President of Operations directly admitted that "the device was always intended for use in the spine." D.Ct.App., Ex. # 14. Finally, AcroMed's President and Chief Counsel admitted, under oath, that AcroMed's plates and screws were designed solely for use in the spine. Third Circuit App. at 58; D.Ct.App., Ex. # 13 at 17.

In reliance on Buckman's misrepresentations, the FDA determined that AcroMed's nested bone plates and cancellous bone screws were substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976. App., 6a. This allowed the plate and screw components to be introduced into the marketplace without being seized by the FDA. Then, in conformity with the fraudulent scheme developed by AcroMed and Buckman, AcroMed marketed the plates and screws solely for use in the spine as a pedicle screw fixation construct. *Id.* This marketing was done

on a massive scale, largely through the promotional efforts of physicians retained by AcroMed pursuant to agreements which afforded these virtual commissioned sales agents the right to participate in the financial growth of AcroMed through very substantial stock options.[5] D.Ct.App., Ex. #s 30, 34, 35, 36 & 37. Other manufacturers adopted the Buckman-AcroMed scheme.

---

[5] Such unlawful marketing resulted in FDA sanctions including withdrawal of FDA approval to conduct clinical trials regarding use of the VSP device, the issuance of numerous warning letters, and the convening of a grand jury investigation. D.Ct.App., Ex. #s 71 & 72. *See also* 63 *Fed.Reg.* at 40037-38. Notwithstanding these enforcement efforts, the marketing scheme adopted by AcroMed and other manufacturers was so successful that pedicle screw fixation gained a foothold among a segment of spine surgeons. Beginning in 1994, the FDA launched an investigation to determine whether to reclassify pedicle screw fixation devices. Despite the fact that the devices had been the subject of at least 14 different clinical trials to assess their safety and efficacy and widespread "off-label" use, the FDA concluded in 1998 that there was insufficient evidence that devices were sufficiently safe or effective to justify their reclassification for treatment of all but a handful of spinal maladies. Even for such indications, however, the agency mandated that the devices would be subject to special controls in regard to labeling, design, material composition, and biocompatibility. *See* "Orthopedic Devices: Classification & Reclassification of Pedicle Screw Spinal Systems," 63 *Fed.Reg.* 40025 (1998). Accordingly, the regulation cannot be viewed as an endorsement with regard to the safety and effectiveness of pedicle screw fixation devices generally or as a ratification of past illegal conduct which brought these devices into the hands of physicians for use in spinal surgery. *See* 63 *Fed.Reg.* at 40037-38.

C. The Proceedings Below

Many people were injured as a result of the spinal application of AcroMed's hardware for pedicle screw fixation. In the product liability litigation which resulted, some of these plaintiffs named Buckman as a defendant based on the theory that Buckman's fraud on the FDA gave rise to actionable injuries under state law.[6]

The District Court, sitting as the MDL transferee forum for all federal pedicle screw cases, dismissed these "fraud-on-the-FDA" claims under *Fed.R.Civ.P.* 12(b)(6). In doing so, it explicitly recognized that such fraud claims were not preempted, particularly in light of this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). However, the District Court decided that allowing a fraud-on-the-FDA claim would essentially create a private right of action for violation of the FDCA and that, "in view of the FDA's exclusive prosecutorial discretion...any grant of an

---

[6] While the issue has not been widely decided, state law appears to recognize a cause of action where a fraudulent misrepresentation induces a regulatory agency charged with the protection of the public to issue an authorization in the form of a permit, clearance, license or the like and the activity conducted pursuant to the regulatory authorization produces physical harm. *See, e.g., Learjet Corp. v. Spenlinhauer,* 901 F.2d 198, 202-03 (1st Cir. 1990) (allowing aircraft purchaser's claim against manufacturer based on misrepresentations to the Federal Aviation Administration); *Stanton by Brooks v. Astra Pharmaceutical Products, Inc.*, 718 F.2d 553, 568-69 (3d Cir. 1983) (allowing patients' claims against drug manufacturer based on misleading statements made to the FDA); *Hawkins v. Upjohn Co.*, 890 F. Supp. 609, 612 (E.D. Tex. 1994) (same).

implied private right of action would be contrary to the letter and spirit of the statute." App., 37a.

On appeal, Buckman sought to justify the District Court's opinion on its own terms and never asserted that state-law claims based on agency fraud were preempted, either expressly or impliedly. However, Sofamor Danek Group, a manufacturer of various pedicle screw fixation devices, appeared in the Court of Appeals as amicus curiae. Sofamor Danek argued that plaintiffs' fraud-on-the-FDA claims were impliedly preempted. No one argued for express preemption under 21 *U.S.C.* § 360k.

The Court of Appeals reversed, holding that no principle of federal law prevented plaintiffs from proceeding with state-law claims which were predicated upon Buckman's alleged misrepresentations to the FDA. The reasoning in support of this holding was straightforward.

First, the Court of Appeals held that "[a]bsent preemption by federal law...a district court cannot decline to enforce liability imposed by the relevant state common law." App., 14a. Second, it recognized that preemption is a matter of legislative intent and that "where Congress has expressed itself on preemption in a statute," Congress' preemptive intent is primarily "discerned from the language of the preemption statute and the 'statutory framework' surrounding it." App., 15a. Third, the Court recognized that the MDAs contain an express preemption provision, 21 *U.S.C.* § 360k, which was definitively construed by this Court in *Lohr* as manifesting a congressional intent to allow states to provide "a traditional damages remedy for violations of common law duties when those duties parallel federal requirements." App., 16a, *citing Lohr*, 518 U.S. at 495. Because plaintiffs' claims were based on a common-law duty to refrain from making misrepresentations which is identical to the duty imposed by federal

law to refrain from making misrepresentations to the FDA, the Court concluded that "the state common law relied upon does not impose any obligation on Buckman inconsistent with federal law" and accordingly was not preempted.[7] App., 13a.

REASONS TO DENY THE WRIT

A. The Question Presented by Petitioner is Not an Issue in This Case

The principal question which Buckman seeks to present to the Court by its Petition for Certiorari is "Whether a state tort claim collaterally attacking a decision of the Food and Drug Administration to permit the marketing of a medical device on the ground that the approval was obtained through a 'fraud on the agency' is expressly and impliedly preempted by the Medical Device Amendments to the Food, Drug and Cosmetic Act." This "question" has nothing whatsoever to do with this case. The plaintiffs here did not seek, and the Court of Appeals did not authorize, any "attack" on any decision by the FDA, collateral or otherwise. Rather, plaintiffs simply contended, and the Court of

---

[7] The Court of Appeals also observed that:

> We do not rule out the possibility that there may be some areas of preemption outside the scope of Section 360k based on clear and direct conflicts between the requirements of state law and those of the FDCA. The existence of Section 360k, its relatively narrow scope and *Lohr*'s presumption against preemption of areas traditionally occupied by state law, however, counsel caution in finding implied preemption where no express preemption exists. App., 18a.

Appeals agreed, that there was nothing in federal law which precluded plaintiffs from seeking damages for injuries proximately caused by fraud committed on the FDA to the extent that state law would permit such recovery. Thus, the question which Buckman seeks to present for the Court's review has nothing to do with the question actually presented and decided in this case. Thus, it is non-justiciable. *Princeton University v. Schmid*, 455 U.S. 100, 103 (1982) (Supreme Court does not sit to decide hypothetical issues or to give advisory opinions); *Hall v. Beals*, 396 U.S. 45, 48 (1969) (same).

B. The Court of Appeals Decision Represents a Straightforward Application of a Recent, Unanimous Ruling by this Court

Certainly, this Court's certiorari powers are properly exercised to bring clarity to the resolution of important issues of federal law where the appellate judicial dialogue has been unable to do so. *See, e.g., Ingalls Shipbuilding, Inc. v. Director, Office of Workers' Compensation Programs Dept. of Labor*, 519 U.S. 248, 254-55 (1997); *Seminole Tribe of Florida v. Florida*, 517 U.S. 44, 45 (1996). However, where the Court has recently exercised such review powers to articulate guiding legal principles with respect to the appropriate interpretation of a federal statute, it is plainly inappropriate to invoke the re-exercise of the Court's review powers to patrol the implementation of those principles by the lower courts. *Rivers v. Roadway Express, Inc.*, 511 U.S. 298, 312-13 (1994). And, it is particularly inappropriate to do so where the decision for which certiorari review is sought involves a straightforward application of a recent, unanimous ruling by this Court. Yet, that is precisely what the instant Petitioner asks of this Court.

The MDAs include an express preemption provision, 21 *U.S.C.* § 360k. Section 360k states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement -- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device....

Before this Court's decision in *Lohr*, most of the Courts of Appeals held that the available FDA marketing clearances or approvals (*i.e.*, investigational device exemptions, 510k clearances and premarket approvals) as well as general FDA labeling and manufacturing regulations, constituted preempting "federal requirements" under Section 360k which totally displaced the availability of common-law tort remedies which were construed as preempted "state-law requirements."[8] As a necessary consequence of this view, they ruled that under section 360k, "states have no authority to police [a manufacturer's] compliance with the FDA's

---

[8] *E.g., Mitchell v. Collagen Corp.*, 67 F.3d 1268 (7th Cir. 1995), *vacated*, 518 U.S. 1030 (1996); *English v. Mentor Corp.*, 67 F.3d 477 (3d Cir. 1995), *vacated*, 518 U.S. 1030 (1996); *Lohr v. Medtronic, Inc.*, 56 F.3d 1335 (11th Cir. 1995), *aff'd in part, rev'd in part*, 518 U.S. 470 (1996); *Michael v. Shiley Inc.*, 46 F.3d 1316 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995), *rejected by Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), *overruled by In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3rd Cir. 1998); *Reeves v. AcroMed Corp.*, 44 F.3d 300 (5th Cir.), *cert. denied*, 515 U.S. 1104 (1995); *Gile v. Optical Radiation Corp.*, 22 F.3d 540 (3d Cir.), *cert. denied*, 513 U.S. 965 (1994); *King v. Collagen Corp.*, 983 F.2d 1130 (1st Cir.), *cert. denied*, 510 U.S. 824 (1993).

procedures." *E.g., Michael*, 46 F.3d at 1329.[9] This view was buttressed by the observation that the FDCA did not expressly or impliedly afford a private damage."[10] Thus, these courts ruled that state-law claims based on violations of FDA regulations, including fraud on the FDA, were preempted by Section 360k.[11]

The decision of this Court in *Lohr* completely rejected both the rulings and the underlying reasoning of this body of federal appellate law. *Lohr* involved claims of preemption with respect to a medical device which, like the devices at issue here, had been cleared for commercial distribution pursuant to the 510k premarket notification process. *Lohr*, 518 U.S. at 470. Although the Petitioner characterizes *Lohr* as a "fractured four-one-four" opinion, the decision of the Court was unanimous in two important respects.

---

[9] *See also Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28-29 (1st Cir. 1995), *cert. dism'd*, 517 U.S. 1230 (1996); *English*, 67 F.3d at 482-83; *Mitchell I*, 67 F.3d at 1283; *Lohr*, 56 F.3d at 1343; *Reeves*, 44 F.3d at 306; *Gile*, 22 F.3d at 544; *King*, 983 F.2d at 1140.

[10] *Lohr*, 56 F.3d at 1343; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 307; *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988, 992 n.2 (8th Cir. 1994); *Gile*, 22 F.3d at 544; *King*, 983 F.2d at 1140.

[11] *Mitchell I*, 67 F.3d at 1283; *Talbot*, 63 F.3d at 28-29; *Lohr*, 56 F.3d at 1343; *Michael*, 46 F.3d at 1329; *Reeves*, 44 F.3d at 306; *Gile*, 22 F.3d at 544. Contrary to Petitioner's assertion, all of these cases were based on express preemption under Section 360k, not on any principle of implied preemption.

First, all of the members of the Court agreed that while the FDA is required to examine 510k notifications with a concern for safety and effectiveness, nothing in the statute requires it to make a determination that the device at issue is safe or effective. *Lohr*, 518 U.S. at 493-94 (majority) & 513 (O'Connor, J., concurring in part). Therefore, all of the members of the Court agreed that a 510k clearance determination by the FDA does not represent a "requirement" sufficient to displace state law. *Id.*

The consequences of this aspect of *Lohr* for the present case are clear. Just as there is nothing in the statute or regulations regarding the 510k notification process which requires the FDA to come to a specific conclusion regarding device safety in terms of the design, labeling or manufacture of devices, there is nothing in the statute or regulations which requires the agency to evaluate the truthfulness of a 510k submission with respect to intended use or any other matter. *See* 21 *U.S.C.* §§ 360c(f)(1), 360c(i)(1)(A); 21 *C.F.R.* § 807.100. Thus, while the FDA may consider questions of truthfulness just as it may consider questions of design safety or labeling adequacy in evaluating a 510k notification, it is not compelled to do so. Therefore, an FDA clearance determination no more represents a preempting "requirement" with respect to the representations made in connection with a 510k notification than it represents a preempting requirement with regard to the design or labeling of a device under *Lohr*, and a liability determination based on such representations under state law would no more represent an impermissible "collateral attack" on the FDA's 510k determination than it did in *Lohr*.[12]

---

[12] *See, e.g., Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110, 118-19 (1996) (holding that while premarket approval is a specific requirement which determines adequacy of device design and labeling and therefore preempts state-law design and labeling (continued...)

The second area of unanimity in *Lohr* which is significant here was the Court's treatment of the issue of whether Section 360k preempts state-law claims based on conduct which violates the requirements of Federal Medical Device Law. With respect to this issue, the Court explicitly recognized that there is no private right to relief for violations of the FDCA. *Lohr*, 518 U.S. at 487. Notwithstanding this, it unanimously rejected the rationale of those cases which held that Section 360k deprived the states of any authority to "police a defendant's compliance" with FDA regulations. Rather, the Court found that because the MDAs preempt only state-law requirements which are "different from or in addition to" federal requirements and because allowing a remedy for unlawful conduct does not amount to the imposition of a "requirement," the MDAs, by their express terms, do not preempt state-law claims to the extent that they seek damages for alleged violations of federal requirements. *Lohr*, 518 U.S. at 495-97 (majority opinion) and 518 U.S. at 513 (O'Connor, J., concurring in part).[13] In fact, the Court observed, the statutory language of

---

[12] (...continued)
claims, premarket approval does not adjudicate the truthfulness of the information supplied to the FDA and, therefore, does not preempt claims that the manufacturer provided the FDA with false, fraudulent or incomplete information), *cert. denied*, 520 U.S. 1168, 1212 (1997).

[13] In this regard, Justice O'Connor's Opinion states:

> I also agree that the Lohrs' claims are not preempted by § 360k to the extent that they seek damages for Medtronics' alleged violation of federal requirements. Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is (continued...)

Section 360k may manifest an intent to foster state-law claims for violations of FDCA requirements in order to "provide[ ] another reason for manufacturers to comply with ... existing 'requirements' under federal law." *Id.* at 495. *See also id.* at 513 (O'Connor, J., concurring in part) ("to be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal requirements]").

This unanimous ruling literally compelled the conclusion reached by the Court of Appeals here. Federal statutory law expressly prohibits the making of fraudulent statements and representations to federal agencies. *See* 18 *U.S.C.* § 1001. Moreover, FDA regulations expressly require that premarket notifications submitted pursuant to Section 510k contain truthful information. *See* 21 *C.F.R.* § 807.87(j). The basis for plaintiffs' fraud claim is that Buckman and others defrauded the FDA by making false statements to the agency concerning an issue of paramount regulatory concern -- the intended use of AcroMed orthopedic plates and screws. Thus, plaintiffs seek recovery for conduct which violates federal law. If *Lohr* was clear about anything, it was clear that such claims are not preempted. Thus, the decision of the Court of Appeals here reflected a conclusion

---

[13] (...continued)

> "different from, or in addition to" requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude states from imposing different or additional *remedies*, but only different or additional *requirements*.

518 U.S. at 513.

which inevitably followed from recent, unanimous precedent by this Court for which certiorari review is particularly inappropriate.

Perhaps sensing this weakness in its position, Petitioner invokes the principle of implied preemption to attract the Court's attention to the issue of whether plaintiffs may bring a state-law claim for injuries caused by fraud on the FDA. However, the principles of implied preemption are just as clear as the rules of express preemption and equally unavailing to Petitioner here.

Implied preemption is a well-defined, narrowly-construed doctrine that provides for preemption in only two specific, discrete circumstances.

The first circumstance requires a demonstration that it would be impossible to comply with both state and federal law at the same time. *See, e.g., Lohr*, 518 U.S. at 507 (Breyer, J., concurring); *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995); *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963); *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941). A good example of a case warranting this type of implied conflict preemption is where state law would impose liability on a manufacturer for using a label required by federal law. *See, e.g., McDermott v. State of Wisconsin*, 228 U.S. 115, 133-34 (1913); *Moore v. Kimberly-Clark Corp.*, 867 F.2d 243, 245-47 (5th Cir. 1989). Plainly, federal law does not permit or require fraudulent statements or prohibit truthful disclosure of information such that state common-law fraud claims would come into actual conflict with specific federal regulatory requirements. *See Connely v. Iolab Corp.*, 927 S.W.2d 848, 853-55 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997); *Green*, 685 A.2d at 118. Under such circumstances, the assertion of implied "conflict" preemption would be specious.

For the same reason, Petitioner cannot demonstrate the second circumstance which warrants implied preemption -- that "state-law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *See, e.g., Lohr*, 518 U.S. at 507 (Breyer, J., concurring); *Freightliner*, 514 U.S. at 287-88; *Florida Lime*, 373 U.S. at 142-43; *Hines v. Davidowitz*, 312 U.S. at 67. As *Lohr* observed, permitting state-law claims for conduct in violation of federal requirements, such as perpetrating a fraud on the FDA, serves to secure compliance with federal law. *See Lohr*, 518 U.S. at 495 (majority) & 518 U.S. at 513 (O'Connor, J., concurring in part). Thus, permitting a state-law claim for fraud on the FDA serves the objectives of federal law. It does not stand as an obstacle to the accomplishment of those objectives. This conclusion is all the more compelling considering that Congress expressly considered the extent to which FDA actions should displace state law in Section 360k and made an express determination not to preempt state-law claims of the type presented here. *See, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280, 288 (1995); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992). Accordingly, this type of implied preemption is also unavailable here.

For all of these reasons, it is clear that the Court of Appeals decision in the present case represents a straightforward application of clear principles of law which have been firmly established by this Court and does not engender the kind of legal uncertainty which requires resolution by the exercise of this Court's certiorari powers.

C. There is No Substantial Appellate Conflict Concerning Whether "Fraud-on-the-FDA" Claims are Preempted

Every appellate court which has considered the issue after *Lohr* has ruled that state-law claims based on a violation of the MDAs are not preempted as "collaterally attacking" or otherwise usurping the FDA's function.[14] Consistent with this, virtually every appellate court which has considered the question after *Lohr* has ruled that state-law claims arising from fraud on the FDA are not

---

[14] *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1381-82 (11th Cir. 1999); *Martin v. American Medical Systems, Inc.*, 116 F.3d 102, 104 (4th Cir. 1997); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996); *Reeves v. AcroMed Corp.*, 103 F.3d 442, 447 (5th Cir. 1997); *Chambers v. Osteonics Corp.*, 109 F.3d 1243, 1248-49 (7th Cir. 1997); *Symens v. SmithKline Beecham Corp.*, 152 F.3d 1050, 1055 (8th Cir. 1998); *Committee of Dental Amalgam Manufacturers and Distributors v. Stratton*, 92 F.3d 807, 812-13 (9th Cir. 1996), *cert. denied*, 519 U.S. 1084 (1997); *Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1977); *Niehoff v. Surgidev Corp.*, 950 S.W.2d 816, 822 (Ky. 1997), *cert. denied*, 118 S. Ct. 1187 (1998); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110 (1996), *cert. denied*, 520 U.S. 1168 (1997); *Armstrong v. Optical Radiation Corp.*, 57 Cal.Rptr.2d 763. 768, 772 (Cal. App. 1996); *Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996), *cert. dism'd*, 520 U.S. 1260 (1997); *Walker v. Johnson & Johnson Vision Products Inc.*, 217 Mich.App. 705, 719, 552 N.W.2d 679, 686 (Mich.App. 1996); *Steele v. Collagen Corp.*, 63 Cal.Rptr.2d 879 (Cal.App. 1997).

preempted.[15] Thus, the status quo does not present the kind of judicial conflict which suggests a need for certiorari review. Nevertheless, Buckman posits that there is a serious division in the Courts of Appeals over whether fraud-on-the-FDA claims are undone by federal law. Plainly, this is not the case.

The sources which Buckman uses in an attempt to generate the appearance that there is a serious judicial debate warranting a unifying resolution by this Court simply don't bear the weight of that effort. *Kuiper v. American Cyanamid Co.*, 131 F.3d 656 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1839 (1998), was a case involving express preemption under FIFRA. It did not involve any claim of fraud on any agency and is so obviously unrelated to the issues here that it was not cited by Buckman in any of the proceedings in the Court of Appeals. *Lewis v. Brunswick Corp.*, 107 F.3d 1494 (11th Cir. 1997), *cert. dism'd*, 118 S. Ct. 1793 (1998), involved the Coast Guard's enforcement of the Federal Boat Safety Act and is so unrelated to the issues raised here that neither Buckman nor its amici cited the case in their briefs or at oral argument in the Court of Appeals. Moreover, to the extent that *Lewis* found that damage claims arising from fraud on the Coast Guard were preempted, it did so without citation to or discussion of a single legal authority. *See Lewis*, 107 F.3d at 1505. Similarly, while the Seventh Circuit ruled in *Mitchell II* that fraud-on-the-FDA claims were preempted, it did so only in passing, without expressing any legal reasons for this conclusion and

---

[15] *See, e.g., In re Orthopedic Bone Screw Products Liability Litigation*, 159 F.3d 817 (3d Cir. 1998); *Green v. Dolsky*, 546 Pa. 400, 685 A.2d 110,117-18 (1996); *Connelly v. Iolab Corp.*, 927 S.W.2d 848, 855 (Mo. 1996); *Dutton v. AcroMed Corp.*, 691 N.E.2d 738, 811-12 (Ohio App. 1997); *Baird v. American Medical Optics*, 713 A.2d 1019, 1030 (N.J. 1998).

without citing any authority to support it other than a pre-*Lohr* decision by the Third Circuit which was subsequently found by that Court to have been overruled in *Lohr*.[16] *See Mitchell v. Collagen Corp.*, 126 F.3d 902, 914 (7th Cir. 1997), *cert. denied*, 118 S. Ct. 1300 (1998). Finally, although Judge Cowen's dissent in this case discusses policy considerations which might be raised in a legislative debate concerning preemption, nothing in his dissenting opinion discusses the applicable legal standards for determining whether Congress has, in fact, manifested a legislative intent to preempt state-law claims or attempts to explain why such standards would require preemption in the circumstances presented here. App., 25a-32a.

Thus, Buckman has failed to point to any source which indicates that there is a genuine, reasoned, legal debate concerning the matters at issue here which exists at the appellate level, let alone one that has matured to the point that Supreme Court intervention is appropriate.

---

[16] In reaching its conclusion, the Court in *Mitchell II* relied on the Third Circuit's pre-*Lohr* ruling in *Michael v. Shiley*, 46 F.3d 1316 (3d Cir. 1995). In the instant case, one of the authors of the Third Circuit's *Michael* Opinion found that it had been overruled by *Lohr*. App., 16a-17a. Given this, the Seventh Circuit may well recede from its perfunctory ruling that fraud-on-the-FDA claims are preempted if it is given the opportunity to do so. Further, *Mitchell II* involved preemption with respect to a device which reached the market through premarket approval and not through 510k clearance. While the preemptive implications of premarket approval may be ambiguous, *Lohr* clearly established that an FDA decision to issue a 510k clearance is not preemptive. Consequently, *Mitchell II* is distinguishable on this basis.

D. This Case Does Not Present An Appropriate Vehicle to Resolve Any Conflict Regarding the Issue of Whether an FDA Marketing Approval Can Preempt State Laws of General Applicability

It is true that the Court in *Lohr* did not resolve by a clear majority the question of whether there can ever be preemption of state tort laws of general applicability under Section 360k. 518 U.S. at 504-05 & 509 (Breyer, J., concurring in part). Moreover, while the Court in *Lohr* held that a 510k clearance will not be preemptive, it did not by a clear majority express any principle sufficient to resolve the question of whether other FDA device marketing "approvals" -- specifically, an investigational device exemption or a premarket approval[17] -- qualify as preempting federal "requirements" for purposes of Section 360k. *Id.* In practical terms, this has left open the question of whether an FDA decision to grant a premarket approval or an investigational device exemption preempts product liability claims relating to the devices which are subject to such approvals. And the Courts of Appeals are, to some extent, divided as to the resolution of that question.[18]

---

[17] Under the statute, the FDA may not grant premarket approval unless it finds that there is "reasonable assurance that [the] device is safe under the conditions of use prescribed, recommended or suggested in the proposed labeling thereof." *See* 21 *U.S.C.* § 360e(d)(2). Similarly, an IDE will only be granted where the applicant satisfies a number of express statutory conditions relating to the safety of the proposed experimental device use. *See* 21 *U.S.C.* § 360j(g); 21 C.F.R. § 813, *et seq.*

[18] *Compare, e.g., Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (no preemption) *with Papike v. Tambrands Inc.*, 107 F.3d 737, 742 (9th Cir.), *cert. denied*, 118 S. Ct. 166 (1997) (continued...)

It is not clear that this division has reached the point that Supreme Court intervention is required to clarify the law. However, if the issue is to be decided by the Court, it should not be resolved as an abstract proposition of law but as part of a controversy in which its resolution will actually make a difference to the outcome. *Princeton University v. Schmid*, 455 U.S. 100, 103 (1982); *Hall v. Beals*, 396 U.S. 45, 48 (1969). This is not such a case.

First, this case does not present the real question engendered by the cited intercircuit split -- whether an IDE or PMA can be preemptive -- because this case only involves a 510k clearance. Second, even if this Court were to conclude that generally applicable tort law could be preempted by some federal requirements under the MDAs, there would still be no preemption of plaintiffs' claims against Buckman. This is because those claims are based on a violation of federal law and because this Court unanimously held in *Lohr* that such claims are not preempted.

Thus, this case does not present a proper vehicle to resolve the broad question of whether state laws of general applicability can be preempted by an FDA requirement or the relevant subsidiary question of whether an FDA decision to grant a premarket approval or investigational device exemption is preemptive of state tort claims arising from the use of a device which is subject to such an exemption or approval.

---

[18] (...continued)
(preemption) ; *Martin v. Telectronics Pacing Systems, Inc.*, 105 F.3d 1090, 1099 (6th Cir. 1997), *cert. denied*, 118 S. Ct. 850 (1998) (same); *Duvall v. Bristol-Myers-Squibb Co.*, 103 F.3d 324, 330 (4th Cir. 1996) (same).

CONCLUSION

For the foregoing reasons, Respondent respectfully submits that the Petition for Certiorari should be denied.

Respectfully submitted.

JOHN J. CUMMINGS, III
Cummings Cummings & Dudenhefer
416 Gravier Street
New Orleans, LA 70130
(504) 586-0000

ARNOLD LEVIN
MICHAEL D. FISHBEIN*
* *Counsel of Record*
SANDRA L. DUGGAN
MICHAEL S. TARRINGER
Levin Fishbein Sedran & Berman
510 Walnut Street, Suite 500
Philadelphia, PA 19106
(215) 592-1500